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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,465	01/05/2006	Giuseppe Giannini	2818-254	1374
23117	7590	07/25/2007		
NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			EXAMINER CHENG, KAREN	
			ART UNIT 1626	PAPER NUMBER
			MAIL DATE 07/25/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/563,465	Applicant(s) GIANNINI ET AL.	
	Examiner Karen Cheng	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 3-10 and 12-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 11 is/are rejected.
- 7) ☒ Claim(s) 1,2 and 11 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 January 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

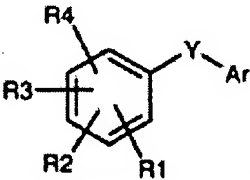

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|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>01/05/06</u> . | 6) <input type="checkbox"/> Other: _____ |

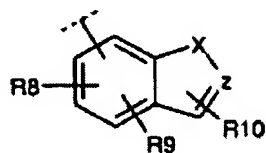
DETAILED ACTION

Claims 1-18 are currently pending in the instant application. Claim 18 has been cancelled. Claims 3-10 and 12-17 have been withdrawn from consideration as being drawn to non-elected subject matter.

Election/Restriction

Applicants' election of Group (III), claims 1, 2 and 11, with traverse directed to

compounds of formula (I)  wherein Y is , Ar is



, X is O, Z is CH, and the rest of the variables are as defined in a paper filed 06/25/2007 is acknowledged. Applicant argues that once the products claims are found allowable, the non-elected claims directed to methods of using the elected compound be rejoined. The Examiner has considered the Applicant's request, and due to the following rejections made on the product claims, the method of use claims have not been rejoined.

Priority

The application is a 371 of International Application No. PCT/IT04/00373, filed on 07/06/2004, which claims the benefit of foreign priority under 35 U.S.C. 119, to Italian Application No. RM2003A000355, filed on 07/18/2003.

Information Disclosure Statement

Applicant's Information Disclosure Statement filed on 01/05/06 has been considered. Please refer to Applicant's copies of the 1449 submitted herewith.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 contains the substituent OCH₂O. It is unclear what can be encompassed by this substituent as the second O does not have a terminal group.

Claim 2 appears to contain compounds that are a literal translation into English from a foreign document. For example, the term "etilendioxy-phenil-1-yl" found in the names of several compounds appears to be a direct translation from a foreign language.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

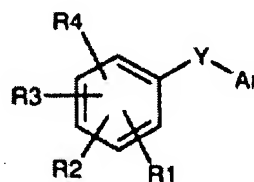
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

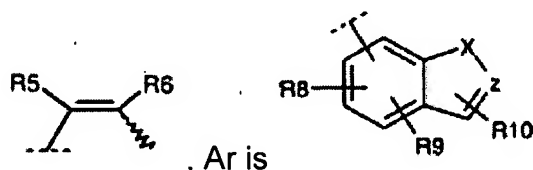
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawai *et al* (see US Patent No. 5,858,995).

Applicants' instant elected invention in claims 1 and 11 teach compounds and



pharmaceutical compositions of formula (I) wherein Y is

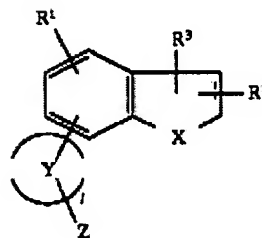


, Ar is

, X is O, Z is CH, and the rest of the variables are

as defined

Determination of the scope and content of the prior art (MPEP §2141.01)



Kawai *et al* teach the compounds of formula

wherein Y is

vinylene, Z is aryl, and X is O, specifically the compound 7-[2-(2,6-

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dichlorophenyl)ethenyl]-2,3-dimethylbenzo[b]furan (see column 56, lines 54-55) and pharmaceutical compositions containing said compounds (see column 30, lines 30-40).

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the prior art of Kawai *et al* and the instantly claimed compounds of applicant is that the invention of Kawai *et al* is directed to compounds wherein Z (as defined in the instant claims) represents a CCH₃ rather than Z is CH, which is claimed in the instant invention.

Finding of prima facie obviousness- rational and motivation (MPEP §2142-2143)

Kawai *et al* is analogous art because compounds of the same structural formula that differ only by the replacement of a methyl for a hydrogen atom would be obvious. As stated in re Wood, 199 USPQ 137, hydrogen and methyl are deemed obvious variants, and substitution of a hydrogen for the methyl (i.e. substitution of CH for CCH₃) in the Z position of the compounds of Kawai *et al* would give rise to the compounds of the instant claims. In the absence of unexpected results, one skilled in the art would expect that the instant claims which are directed to compounds and pharmaceutical composition that are analogous to the compounds and pharmaceutical compositions of Kawai *et al* is prima facie. The motivation to synthesize the claimed compounds derives from the expectation that structurally similar compounds are generally expected to have similar properties and have similar utilities, and the compounds of Kawai *et al* are disclosed to have pharmaceutical use. The explicit teaching of Kawai *et al* together with the enabled examples would have motivated one skilled in the art to synthesize the

known compounds for the treatment of bone diseases with such generic teaching with the expectation that they would all have similar utility as taught by Kawai *et al*

Claim Objections

Claim 1 is objected to because of the following informalities: The R10 substituent appears that it can be in multiple locations. However since Z is CH, R10 can only be substituted on the carbon next to Z. Appropriate correction is required.

Claims 1, 2 and 11 are objected to because of the following informalities: they are dependent on subject matter that has been withdrawn from consideration. Appropriate correction is required.

Claim 2 is not written in proper format for a Markush-type claim. Specifically there should be an "and" separating out the last two species. Appropriate correction is required.

Drawings

The drawings are objected to because they fail to show what the white and black bar in the drawings represent. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several

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views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cheng whose telephone number is 571-272-6233. The examiner can normally be reached on M-F, 9AM to 5:30PM EST.

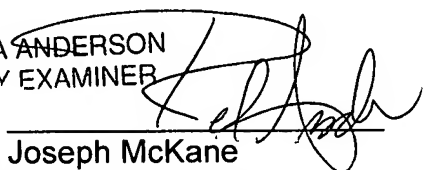
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Karen Cheng
Patent Examiner, AU 1626

REBECCA ANDERSON
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for Joseph McKane
Supervisory Patent Examiner, AU 1626